

c.) Remarks

The specification has been amended in conformity with 35 U.S.C. §120 and §365(c). A claim to benefit of the prior PCT application is already within the Inventors' Declaration of record.

Claim 1 has been amended in order to recite the present invention with the specificity required by statute. Additionally, claims 6, 7, 43, 47, 52, 61, 78-86, 88, 90 and 91 are amended to maintain their dependency and/or for proper antecedent basis. No new matter has been added.

Method claims 47-63, 78, 80-87 and 91, and material claims 79 and 88-90 have been withdrawn from further consideration pursuant to 37 C.F.R. §1.142(b). Rejoinder of these claims is respectfully requested upon allowance of an elected antecedent claim.

Claim 25 is rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. In response, enclosed is a suitable Deposit Declaration averring compliance with the terms of the Budapest Treaty regarding deposit FERM BP-7043.

Claims 29, 30 and 42 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Although this rejection is respectfully traversed, these claims have been cancelled simply in order to reduce the issues and expedite prosecution herein.

Claims 1-46 and 76-77 (sic) are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In response, claims 1 and 7 have been amended to address the Examiner's concern; claims 20 and 45 are cancelled.

Claims 1 and 6-24, 26-39<sup>1/</sup> and 42-46 are rejected under 35 U.S.C. §112, first paragraph, as failing to be supported by an enabling disclosure. The Examiner acknowledges enablement for stem cells isolated from adult mouse bone marrow, which differentiate into cardiomyocyte in the presence of 5-azacytidine, DMSO, PDGF, FGF-8, retinoic acid, ET-1, midkine, BMP4, NKX2.5/CSX and GATA4 but not (1) cells from other organisms that (2) differentiate into cardiomyocyte, adipocyte, skeletal muscle cell, osteoblast or vascular endothelial cells. The Examiner also questions enablement for dependent claims that specify the presence or absence of certain markers, etc.

This rejection is respectfully traversed. In particular, contrary to the Examiner's position, it is understood, based on the specification and the knowledge of the skilled artisan, that an adult bone marrow-derived stem cell can differentiate into a cardiomyocyte not only in a mouse but also, e.g., in a human. See, for instance, *The Journal of Gene Medicine*, 6, 833 (2004); *Society of Experimental Biology and Medicine*, 229, 623 (2004).<sup>2/</sup>

Also, the Examiner contends the specification does not provide any evidence that the differentiated cells functioned as adipocytes, or brain cell or liver cells. In response, Applicants wish to invite the Examiner's attention to Example 13, where the stem cell of the present invention was labeled with GFP, the cells were transplanted into mice with pseudopregnancy, and organs of the born mice were extirpated to observe the expression of GFP in the brain and liver. In Example 13, since GFP expression was observed in the brain cell and the liver cell, it was evidenced that the stem cells differentiated into cells which function as a brain cell or a liver cell.<sup>3/</sup>

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<sup>1/</sup> Apparently, 26-40.

<sup>2/</sup> Copies of these papers are attached to the Information Disclosure Statement filed concurrently herewith.

<sup>3/</sup> As understood, if the cells do not function as a brain cell or a liver cell, the cells  
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